



NATIONAL LABORATORIES UNIT-II
Village & Post Manpura Baddi Nalagarh Road Distt. Solan (H.P.)

Certificate of Analysis (Finished Product)

Product Name	CANDICORT EAR DROPS 05ml	A.R. No.	FP/24/07/130
Batch No.	TLF019	Received Date	21/07/2024
Mfg Date	06/2024	Analysis Date	21/07/2024
Exp Date	05/2026	Sample Qty.	10X05ml
Mfg By	Self	Batch Size	260.0kg.

Sr. No.	Parameter	Specifications	Results	
1.	Description	Clear colourless liquid filled in white coloured plastic bottles.	Clear colourless liquid filled in white coloured plastic bottles.	
2.	Identification	Positive for Beclomethasone Dipropionate, Gentamicin Sulphate, Lignocaine HCl and Clotrimazole	Complies.	
3.	Average Fill Volume	NLT Label amount	5.1888ml	
4.	Uniformity of Volume	±10.00%	(-2.47 to +5.96)%	
Assay: Each composition contains.				
	Composition	Label Claim	Results	Limits
	Gentamicin Sulphate IP Eq. to Gentamicin	0.300%w/v	0.306%w/w 102.00%	0.270 to 0.330%w/v (90% to 110%)
	Beclomethasone Dipropionate IP	0.025% w/v	0.02599% w/v 103.96%	0.0225 to 0.0275% w/v (90% to 110%)
	Clotrimazole IP	1.0% w/v	0.9836% w/v 98.36%	0.9 to 1.1% w/v (90% to 110%)
	Lignocaine HCl IP	2.00% w/v	2.0572% w/v 102.86%	1.80 to 2.20% w/v (90% to 110%)

OUTSIDE LAB:- SELQUET TESTING & RESEARCH LABORATORY PVT.LTD. (GENTAMYCIN SULPHATE)

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Remark: Above analysis has been done as per I.P./B.P./U.S.P./I.H. Specification.

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Ruti	Rinky	Arun Mishra
DESIGNATION	QC-officer	QC officer	QC-Manager
SIGNATURE	Ruti	R	Arun
DATE	21/07/2024	21/07/2024	21/07/2024